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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,502

03/17/2006

Nitin Bhalachandra Dharmadhikari

2867.003US1

4377

21186

7590

09/29/2009

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

09/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com

request@slwip.com

Office Action Summary	Application No. 10/572,502	Applicant(s) DHARMADHIKARI ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/17/06, 4/23/07, 7/7/08, 11/12/08</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/17/06, 4/23/07, 7/7/08 and 11/12/08 were filed in timely fashion. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-30, 32, and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hettche (USPN 5,271,946 hereafter '946).

The '946 patent teaches a oral drug delivery system comprising at least a coated core comprising an active agents and at least a coating surrounding the core, wherein the coating is removed during administration (abstract, col. 4, lin. 58-60). The coating comprises pore forming agents that provide a passageway through the membrane (col. 6, lin. 30-60). Pore formers are present in the outer coating and include gas-forming agents such as carbonates (col. 6, lin. 60-65). The core comprises gas generating agents and is coated with polymers (col. 3, lin. 65-col. 4, lin. 42). These coated cores are then compressed into a tablet and the tablet is coated with a pH-dependent polymer that is semi-permeable (col. 5, lin. 25-45). The core further includes swellable polymers such as osmotic agents and wicking agents (col. 4, lin. 27-41, col. 5, lin. 9-

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25), col. 7, lin. 57-68). The coated granules are in the immediate vicinity of the coating material, forming an in-lay tablet (Example 1). Regarding the release of the active agent, as discussed above the release of the active agent is not well defined in the claim. The '946 patent teaches a coated tablet formulation comprising a core wherein the core comprises same swelling agents as the instant claims. The coating layers of the '946 patent provide a controlled release and would also reliably remove fully when exposed to the appropriate aqueous environment. The release of the active agent is controlled by the addition of components into the core and coating components, all of which are fully taught by the '946 patent. For these reasons any release profile for the coated tablet is possible for the '946 coated tablet. For these reasons the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Hettche (USPN 5,271,946 hereafter '946) in view of Burnside et al (USPN 6,322,819 hereafter '819).

As discussed above the '946 patent discloses a formulation comprising a coated tablet wherein the core comprises swellable polymers and coating completely surrounds the core. The core further comprises swellable polymers, wicking agents and osmotic agents.

The reference is however silent to further active drug coating layers in the same formulation. This additional coating layer is well known in the art in order to provide a combination release where an immediate burst is required and a more delayed or prolonged release of another or similar drug is required. This can be found in the '819 patent.

The '819 patent discloses an oral formulation comprising a core wherein the core comprises a dry layer and excipients (abstract, col. 6, lin. 50-68). The core is further coated with a protective layer, followed by a separate drug layer (col. 7, lin. 45-68). The dosage form is then coated with another protective layer comprising an enteric polymer (claims). One drug layer is released immediately upon administration and the other drug layer is released in a controlled manner over time (col. 3, lin. 25-40). The drugs in each layer may be the same or different (claims). The cores can be either compressed into a tablets (col. 7, lin. 1-5). It would have been obvious to add an additional layer of drug to the coated cores of the '946 patent in order to provide an immediate relief to the patient while providing longer timed relief such as a nighttime administration.

With these things in mind it would have been obvious to combine the prior art with an expected result of a pulsatile release dosage form useful for nighttime administration. It would

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have been obvious to add an additional immediate release layer as shown in the '819 patent to the coated cores of the '946 patent since the '946 patent is suggestive of other active agents in addition to the core drug (col. 10, lin. 32-39), and an additional layer would provide expand the administration options for the formulation. It would have been obvious to combine the prior art as discussed with an expected result of a stable controlled release formulation useful for nighttime administration.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/
Examiner, Art Unit 1618